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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,553	TOBIN ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *1,6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-7 are pending.

2. Applicant's election with traverse of Group II, claims 2-5 in the paper filed 11/03/2003 acknowledged. The traversal is on the ground(s) that Applicant contends that an examination of all the claims would not create an undue burden even though the claims are directed to independent and distinct inventions. This is not found persuasive because while the search of the prior art for one group may overlap with that of another, they are not co-extensive of each other and thus would be a burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, and 6-7 have been withdrawn from consideration because the claims are drawn to non-elected inventions.

3. Claims 2-5 are examined in the present office action.

Specification

4. The "Brief Description of the Drawings" is objected to because Applicants have submitted Figures 2A-2G, 7A-7B, 11A-11B, and 12A-12B but the Brief Description of the Drawings only specifies Figures 2, 7, 11, and 12. Applicants are requested to amend the Brief Description of the Drawings to include Figures 2A-2G, 7A-7B, 11A-11B, and 12A-12B.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide comprising a polynucleotide which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3, a method of altering plant development comprising transforming a plant with a nucleic acid sequence which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3, or a transgenic plant comprising a nucleic acid sequence which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3.

Applicants present the complete cDNA clone as set forth in SEQ ID NO:3 and the complete genomic sequence as set forth in SEQ ID NO:1 the name of which is CCA1 (page 12, 1st and 2nd paragraph).

Applicants do not describe any polynucleotide sequences that hybridize to and which are at least 95% complementary to SEQ ID NO:1 or 3 that encode a functional CCA1 protein.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a

genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of polynucleotide sequences encoding a CCA1 protein falling within the scope of the claimed genus of polynucleotides which hybridize to and which are at least 95% complementary to SEQ ID NO:1 or 3. Applicants only describe a single cDNA (SEQ ID NO:1) and its corresponding genomic sequence (SEQ ID NO:3). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for CCA1 protein activity, it remains unclear what features identify a CCA1 encoding polynucleotide. Since the genus of CCA1 encoding polynucleotides has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that hybridize with SEQ ID NO:1 or 3 and which are 95% complementary to SEQ ID NO:1 or 3 encompass naturally occurring allelic variants, mutants of CCA1 protein, as well as sequences encoding proteins having no known CCA1 activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the hybridization language or percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Scope of Enablement

6. Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims drawn to the isolated polynucleotide of SEQ ID NO:1 or 3, method of increasing hypocotyl length and method of delaying flowering by transforming with said polynucleotides, and transgenic plants with an increased hypocotyl length and delayed flowering produced thereby, does not reasonably provide enablement for claims drawn to an isolated polynucleotide which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3, method of altering plant development by transforming with said polynucleotides or plants with altered development produced thereby. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to an isolated polynucleotide comprising a polynucleotide which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3, a method of

altering plant development comprising transforming a plant with a nucleic acid sequence which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3, or a transgenic plant comprising a nucleic acid sequence which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3.

Applicants provide guidance for screening of an expression library made from *Arabidopsis* leaves with the radiolabeled A2 fragment of the *Lhcb1**3 promoter and a mutant probe (m1) that is known to poorly bind to CA-1 (page 10, 2nd paragraph), and isolation of two plaques that bound to the A2 probe but not the m1 probe. Applicants teach the complete cDNA clone as SEQ ID NO:3 and the complete genomic sequence as SEQ ID NO:1 the name of which is CCA1 (page 12, 1st and 2nd paragraph). Applicants further teach transformation of Arabidopsis with a sequence encoding the CCA1 protein (it is not specified which SEQ ID NO is used) operably linked to the 35S promoter, and Applicants report that hypocotyl length is increased (page 32, top paragraph) and the time to flowering is delayed (page 33, bottom paragraph). The specification fails to provide guidance for the isolation or synthesis of other polynucleotides encompassed by the claims that encode CCA1. Applicants fail to teach which amino acids can be deleted or altered and still produce a protein with the same function as the protein encoded by SEQ ID NO:1 or 3.

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that are 95% sequence identical to SEQ ID NO:1 or 3 will encode a protein with the same activity as a protein encoded by SEQ ID NO:1 or 3. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence

where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 or 3 as probes or by designing primers to undisclosed regions of SEQ ID NO:1 or 3 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those polynucleotides that when over-expressed bind to the *Lhcb1*3* promoter and produce plants with an increased hypocotyl length and delayed time to flowering.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,388,172. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious over the claims of Patent No. 6,388,172. Claims 2-5 of the present application are drawn to an isolated polynucleotide comprising a polynucleotide of SEQ ID NO:1 or 3, a polynucleotide which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3; a method of altering plant development comprising transforming a plant with

a polynucleotide of SEQ ID NO:1 or 3 or a nucleic acid sequence which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3; or a transgenic plant comprising a polynucleotide of SEQ ID NO:1 or 3, or a nucleic acid sequence which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3. Claims 1-4 of U.S. Patent No. 6,388,172 are drawn to an isolated polynucleotide comprising a polynucleotide of SEQ ID NO:1 or 3, a method of altering plant development comprising transforming a plant with a polynucleotide of SEQ ID NO:1 or 3, or a transgenic plant comprising a polynucleotide of SEQ ID NO:1 or 3. Therefore the claims of the present application encompass claims 1-4 of U.S. Patent No. 6,388,172, and are obvious in view of the issued patent.

8. Claims 2-5 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1 or 3 or a sequence which hybridizes to and which is at least 95% complementary to SEQ ID NO:1 or 3, method of altering plant development comprising an above recited sequence or plant transformed therewith.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

January 23, 2004

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